

THE REGENTS OF THE
UNIVERSITY OF CALIFORNIA,

Plain
vs.

VS.

PAUL S. AISEN, et al.,

Defendants.

CASE NO. 15-cv-1766-BEN (BLM)

**ORDER GRANTING
DEFENDANTS' MOTION FOR
CLARIFICATION OR
MODIFICATION OF THE
PRELIMINARY INJUNCTION**

I. INTRODUCTION

Now before the Court is Defendants' Motion to Clarify or Modify the Preliminary Injunction Issued by the State Court. Defendants allege that changed circumstances necessitate modification, or at least, clarification of the preliminary injunction order. Plaintiff disagrees. The evidence suggests that circumstances have changed significantly since the time the preliminary injunction order was entered. Moreover, the Special Master has asked for clarification. At least clarification, and perhaps modification is necessary. Therefore, the motion is granted.

II. APPLICABLE LAW

The Supreme Court teaches that when questions arise as to the interpretation or application of an injunction order, a party should seek clarification or

1 modification from the issuing court, rather than risk disobedience and contempt.
2 *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 192 (1949) (“Yet if there were
3 extenuating circumstances or if the decree was too burdensome in operation, there
4 was a method of relief. . . . Respondents could have petitioned the District Court for
5 a modification, clarification or construction of the order.”); *Regal Knitwear Co. v.*
6 *NLRB*, 324 U.S. 9, 15 (1945) (“If defendants enter upon transactions which raise
7 doubts as to the applicability of the injunction, they may petition the court granting
8 it for a modification or construction of the order.”). Defendants filed this motion for
9 clarification or modification shortly after circumstances changed and not long after
10 questions were raised by the Special Master. Because “courts no less than parties
11 desire to avoid unwitting contempts,” *Regal*, 324 U.S. at 15, clarification or
12 modification is warranted.

13 **III. THE PRELIMINARY INJUNCTION ORDER**

14 The difficulty with this type of case stems from the medical delicacy and
15 technological complexity of the Alzheimer’s Disease Cooperative Study (“ADCS”)
16 Data and Systems which are the subject of the preliminary injunction order. The
17 preliminary injunction was crafted in such a way as to safeguard from destruction a
18 significant public resource: longitudinal medical research and its informational
19 databases about treatments for Alzheimer’s Disease. Because the informational
20 databases include computer data files, they must be managed by experts in digital
21 technology. Because the studies are ongoing, disruptions in data access or loss of
22 data may have serious adverse impacts on patients today.

23 On August 4, 2015, a preliminary injunction was issued on the basis that
24 Plaintiff “has demonstrated ownership and a right to control and manage certain
25 data and systems, the control and management of which have been taken over by
26 Defendants.” (Preliminary Injunction at 1-2.) The ADCS Systems and Data were
27 ordered transferred to the “possession, custody, and control of UCSD and its duly
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1 authorized employees, *consistent with the terms of the contracts and grants to*
2 *which UCSD is a party.*" (*Id.* at 2 (emphasis added).) The Special Master is "to
3 ensure that the process is completed in a comprehensive, technically appropriate,
4 and timely manner, and without prejudicing UCSD, or causing any avoidable risk of
5 harm to the rights or interests of third parties." (*Id.* at 3-4.)

6 The preliminary injunction order anticipates change. It anticipates that a
7 study sponsor (the term "third party" is used in the text) may assign its rights to
8 obtain access, custody, or control over the ADCS data, and it may assign its rights
9 to the Defendants. At the time the preliminary injunction issued, Plaintiff was
10 responsible for managing all of the ADCS studies.

11 Not long after, however, five of the six major study sponsors transferred their
12 studies to Defendant University of Southern California. The five major studies are
13 the FYN study with Yale, the INI study with Wake Forest, the two ADNI Studies,
14 and the A4 Study with Lilly. In addition to the five major studies, another study,
15 LEARN, which is an offshoot of the major A4 Study, has also transferred to
16 Defendant University of Southern California. Defs.' Mot. to Clarify or Modify,
17 Aisen Decl. ¶ 37, Exs. J, K, & L; Barton Decl. ¶ 6; Sperling, M.D., Decl. ¶ 4. As a
18 result, by maintaining custody and control over some ADCS Systems and Data,
19 Defendants may be acting in compliance with the preliminary injunction by virtue
20 of acting in the shoes of the transferred Study Sponsors, while at the same time be
21 violating the order to the extent they are acting on their own behalf. Not only does
22 this make difficult the task of enforcing the ordered return of systems and data to
23 the Plaintiff, it will require a re-transfer of systems and data back to the Defendants
24 for the transferred studies. Medical research is complicated enough. Large scale
25 data management is complicated enough.

26 Defendants filed their motion for clarification or modification only two weeks
27 after questions were raised by the Special Master. *See* Notice of Lodging of Special
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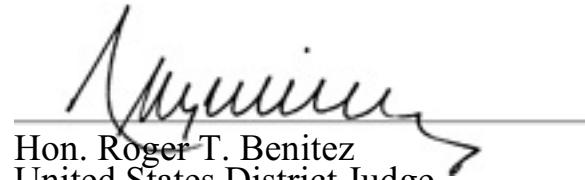
1 Master's Interim Report (9/2/15), Dkt. #14. The Special Master wrote, “[o]n
2 September 2, 2015 the ‘Interim Report of the Special Master and Consultant’ was
3 lodged with this Court by Defendants on the Special Master’s behalf The
4 Interim Report updated the Court on the status of the Special Master’s work, and
5 requested three clarifications of the Preliminary Injunction.” See Notice of
6 Lodging of Directive of the Special Master (9/11/15), at 6, Dkt. #20 (emphasis
7 added). The Defendants need clarification and the Special Master needs
8 clarification.

9 **IV. CONCLUSION**

10 Therefore, the motion is granted. The preliminary injunction order will be
11 clarified or modified if still warranted by the current state of events. However, time
12 has passed since the briefing on the motion. Consequently, the parties are directed
13 to file new briefs.

14 Defendants shall file by October 3, 2016, a new brief setting forth their
15 requested clarifications or modifications. Plaintiff may file a response by October
16 24, 2016. It is requested that the Special Master file a statement setting forth his
17 own requested clarifications or modifications by October 17, 2016. Either party
18 may file a response to the Special Master’s statement by October 31, 2016. A
19 hearing will be set by the Court thereafter.

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21 DATED: August 30, 2016

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23 Hon. Roger T. Benitez
United States District Judge

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